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| APPLICATION NO.       | FILING DATE                 | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
|-----------------------|-----------------------------|----------------------|------------------------------|------------------|
| 10/082,973            | 02/26/2002                  | James S. Norris      | 14017-004002 /PSU<br>96-1566 | 8113             |
| 26161<br>FISH & RICHA | 7590 01/12/200<br>ARDSON PC | EXAMINER             |                              |                  |
| P.O. BOX 1022         |                             | EPPS FORD, JANET L   |                              |                  |
| MINNEAPOLI            | S, MN 55440-1022            |                      | ART UNIT                     | PAPER NUMBER     |
|                       |                             | 1633                 |                              |                  |
|                       |                             |                      |                              |                  |
|                       |                             |                      | NOTIFICATION DATE            | DELIVERY MODE    |
|                       |                             |                      | 01/12/2009                   | ELECTRONIC       |

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

|  |   | Application       | on No.                 | Applicant(s)  |  |  |  |  |
|--|---|-------------------|------------------------|---------------|--|--|--|--|
| Office Action Summary  |   | 10/082,97         | 3                      | NORRIS ET AL. |  |  |  |  |
|  |   | Examiner          |                        | Art Unit      |  |  |  |  |
|  |   | Janet L. E        |                        | 1633          |  |  |  |  |
| The M/<br>Period for Reply   | The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply   |                   |                        |               |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                   |                        |               |  |  |  |  |
| Status   |   |                   |                        |               |  |  |  |  |
| 1)⊠ Pesnon   | sive to communication(s) filed on 3   | 16 October 200    | Q                      |               |  |  |  |  |
| ·  | Responsive to communication(s) filed on <u>16 October 2008</u> .  This action is <b>FINAL</b> 2b \sqrt{1} This action is non final.   |                   |                        |               |  |  |  |  |
| ´=   | This action is <b>FINAL</b> . 2b) This action is non-final.  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |                   |                        |               |  |  |  |  |
| •  | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.   |                   |                        |               |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |   |                   |                        |               |  |  |  |  |
| Disposition of C   | aims  |                   |                        |               |  |  |  |  |
| 4)⊠ Claim(s  | ☑ Claim(s) <u>39-55</u> is/are pending in the application.  |                   |                        |               |  |  |  |  |
| 4a) Of th  | 4a) Of the above claim(s) is/are withdrawn from consideration.  |                   |                        |               |  |  |  |  |
| 5)∭ Claim(s  | 5) Claim(s) is/are allowed.   |                   |                        |               |  |  |  |  |
| 6)⊠ Claim(s  | 6)⊠ Claim(s) <u>39-55</u> is/are rejected.  |                   |                        |               |  |  |  |  |
| 7)☐ Claim(s  | ) is/are objected to.   |                   |                        |               |  |  |  |  |
| 8)☐ Claim(s  | ) are subject to restriction a  | nd/or election re | equirement.            |               |  |  |  |  |
| Application Pape   | ers   |                   |                        |               |  |  |  |  |
| 9)□ The spe  | cification is objected to by the Exar   | miner             |                        |               |  |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.   |   |                   |                        |               |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |                   |                        |               |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.05(a).  |   |                   |                        |               |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |                   |                        |               |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |                   |                        |               |  |  |  |  |
| _  | •   | oian priority up  | 10r 25 11 C C S 110(a) | (d) or (f)    |  |  |  |  |
| •  | 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |                   |                        |               |  |  |  |  |
| ·—   | <ul> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> </ul> |                   |                        |               |  |  |  |  |
|  |   |                   |                        |               |  |  |  |  |
| <u> </u>   |   |                   |                        |               |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |   |                   |                        |               |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  |   |                   |                        |               |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |                   |                        |               |  |  |  |  |
| Attacks (1/2)  |   |                   |                        |               |  |  |  |  |
| Attachment(s)  1) \[ \sum \text{Notice of References Cited (PTO-892)} \]  4) \[ \sum \text{Interview Summary (PTO-413)} \]   |   |                   |                        |               |  |  |  |  |
|  | person's Patent Drawing Review (PTO-948   | 3)                | Paper No(s)/Mail Da    | ate           |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)  5) Notice of Informal Patent Application   |   |                   |                        |               |  |  |  |  |
| Paper No(s)/Mail Date 6)   |   |                   |                        |               |  |  |  |  |

Application/Control Number: 10/082,973 Page 2

Art Unit: 1633

#### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 39-55 are presently pending.

## Response to Amendment/Arguments

#### Claim Rejections - 35 USC § 102

3. The rejection of claims 39-40 and 42-55 under 35 U.S.C. 102(e) as being anticipated by Norris et al. (US <u>20030125280</u>; priority date of December 3, 1996), is withdrawn in response to Applicant's amendment to the claims.

#### Claim Rejections - 35 USC § 103

4. The rejection of claims 39, and 42-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norris et al. (WO 97/17433) in view of Stinchcomb et al. (US 5,599,706), is withdrawn in response to Applicant's amendment to the claims.

### Claim Rejections - 35 USC § 112

- 5. Claims 39-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (New matter).
- 6. It is noted that the above ¶ was included in the prior Office Action, however the grounds for rejection were not set forth. The examiner intended to state that the

Art Unit: 1633

rejection of claims 39-55 under this statue as set forth in the Final Rejection mailed 9/19/2007 was withdrawn.

- 7. However, Applicant's amendment to the claims filed 10/16/2008 raises a new ground of rejection under this statute for the following reasons.
- 8. Claims 39-55 were amended to recite "wherein said autocatalytically cleaving ribozyme comprises SEQ ID NO: 53 or 54." As support for this amendment Applicants made reference to Figure 3, and page 43, line 1 to page 44, line 2. However, there is no specific disclosure of SEQ ID NO: 53 or 54 in the specification as filed, wherein these sequences are isolated sequences, and further wherein these sequences are generically encompassed within the context of any form of "autocatalytically cleaving ribozyme," other than within the context of either SEQ ID NO: 4 or 5. There is no support for claiming this sequence independently, i.e. wherein the sequence is not within the context of SEQ ID NO: 4 or 5. Moreover, the examiner cannot visually find these sequences within the context of the structure of Figure 3. Applicant's amendment to the Specification as filed, and to the claims to include SEQ ID NO: 53-54 is considered new matter.
- 9. The amendment filed 10/18/2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The addition of SEQ ID NO: 53-54 is considered new matter, since these sequences were not independently defined in the specification or claims as filed. These sequences were

only defined as being within the context of SEQ ID NO: 4 or 5. There is no support for extracting these sequences from SEQ ID NO: 4 or 5, and claiming these sequences independently, or adding these sequences to the Sequence Listing as part of the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

#### Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Page 5

11. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-

272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

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USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633

JLE